

“---The material (12, i.e., the ‘reference mask’ or “exoskeleton” as it is referred to by Kormos) is then stretched over and molded to the soft tissue region (of the patient) and affixed by clamps or other suffixing means 14 to sides of the patient support---” (emphasis added).

The claimed invention, on the other hand, does not require that the patient be immobilized relative to a fixed patient support; in fact it specifies that the reference mask system is a “mechanically free” locator. Furthermore, the invention relates specifically to a system that is not only mechanically free but also has the ability to repeatedly be fixed to the patient’s rigid anatomy so that it can be used for repeat procedures. This is specifically not the focus nor the intent of the Kormos patent. In the latter the ‘exoskeleton’ is designed for a one-use application and then is removed and, presumably, discarded. See Col. 5, ll10-12.

The inventive approach, conversely, takes a rigid portion of the patient’s anatomy and by molding a mask to the anatomy extends this rigid anatomical feature so that external fiducials can be applied. It is capable of, indeed, is designed for multiple uses and applications. Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1-8, 10-14, 17-18, and 20-22 over 35 USC 103 as obviously unpatentable over Kormos ‘890 in view of McLaurin is respectfully traversed. Notwithstanding the Examiner’s comments regarding the disclosure of the secondary reference, the fact remains that the reference does not cure the deficiencies pointed out above in connection with the primary reference to Kormos. More particularly, McLaurin does not disclose or suggest the use of a ‘mask’ or ‘exoskeleton’ that is mechanically free, i.e., that is not affixed to the patient support or locator.

The McLaurin patent is, like that of Kormos, an immobilization system for fixing a patient. Applicants specifically discuss ion the specification that

immobilization of the patient is not the preferred method of referencing. This technique has been applied over many years and has shown limited clinical success. The entire focus of the present invention is the use of, e.g., a facemask that is rigid and fixes the patient relative to a second reference system. The proposed improvement of this system is that the second reference system, the bar references, which is similar to those used for stereotactic head frame application, is added to the mask system. The reference bars are relative to the frame system and not the patient. The difficulty in this approach is that it is known that the patient does not repeatedly position in the reference frame mask if the mask is used for immobilization and localization. The reference frame, the bar system, is therefore not rigidly fixed to the patient's anatomy. In the claimed approach we specifically maintain the reference system "mechanically free" to allow the reference system to more precisely reseat to the patient's external anatomy. This separation of immobilization and localization is the key difference between the claimed invention and the prior art approaches.

A legal conclusion of patent invalidity for obviousness must be supported by findings on the four factual inquiries set forth in *Graham v. John Deere Co.*, [383 U.S. 1, 148 USPQ 459 (1966)].

Precedent clearly establishes that the fact-finder must make Graham findings before invalidating a patent for obviousness. See *Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021,1025 (Fed. Cir. 1984)); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 961, 1 USPQ2d 1196, 1200 (Fed. Cir. 1986); In *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 228 USPQ 90 (Fed. Cir. 1985), it was stated:

"---In patent cases, the need for express Graham findings takes on an especially significant role because of an occasional tendency --- to depart from the Graham test, and from the statutory standard of unobviousness that it helps determine, to the tempting

but forbidden zone of hindsight. Thus, we must be convinced --- that---Graham (was actually applied)---" The necessity of Graham findings is especially important where the invention is less technologically complex, [In re Dembicza, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)]. In such a case, the danger increases that the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.---"

Thus, the legal conclusion of invalidity for obviousness depends on four factual inquiries identified by *Graham v. John Deere Co.* as concerning (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness.

In the present case the Examiner has erred by failing to conduct a Graham analysis. Indeed the Examiner has failed to even mention Graham, much less analyze the disclosures of the prior art.

In order to justify a combination of references, it is necessary not only that it be physically possible to combine them, but also that the art should contain something to suggest the desirability of doing so. *Ex parte Walker*, 135 USPQ 195; *Ex parte Fleischmann*, 157 USPQ 155. The prior art cannot be combined as if appellant's invention was included therein as a part of the knowledge possessed by one of ordinary skill in the art. In combining references, the prior art references themselves must suggest their being combined so as to render the claimed invention obvious to one skilled in the art; and resort must not be had to applicant's own disclosure and the utilization of hindsight for the guiding hand that dictates the combination of references.

It is further well settled that the prior art itself must suggest the problem sought to be solved by the claimed invention before it can be said to suggest or

disclose its solution. *In re Shaffer*, 108 USPQ 326; *In re Aufhauser*, 158 USPQ 351; *US v. Adams* 148 USPQ 479; *In re Nomiya*, 184 USPQ 607.

Any analysis of obviousness must necessarily begin in the text of section 103, with the phrase “at the time the invention was made.” For it is this phrase that guards against entry into the “tempting but forbidden zone of hindsight,” [see *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 873; 228 USPQ 90, 98 (Fed. Cir. 1985), overruled on other grounds by *Nobel-pharma AB v. Implant Innovations, Inc.*, 141 F. 3d 1059, 46 USPQ2d 1097 (Fed. Cir. 1998)], when analyzing the patentability of claims pursuant to that section.

Measuring a claimed invention against the standard established by section 103 requires the often difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See, e.g., *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 USPQ 303, 313 (Fed. Cir. 1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one “to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.” *Id.*

The present state of the patent law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F. 3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998,) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an

obviousness holding") *In re Rouffet*, 149 F.3d 1350, 1359; 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically---the reasons one of ordinary skill in the art would have been 'motivated to select the references and combine them'); *In re Fritch* 972 F.2d 1260, 1265; 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075; 5 USPQ2d 1596, 1600 (Fed Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham* 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board (Examiner) has obviously fallen into the hindsight trap.

Courts have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 751 F.3d 1568, 1573; 37 USPQ2d 1626, 1630 (Fed. Cir. 1996), *Para-Ordnance Mfg. v. SGS Imports Intern., Inc.*, 73 F.3d 1085, 1088; 37 USPQ2d 1237, 1240 (Fed. Cir. 1995),

although “the suggestion more often comes from the teachings of the pertinent references,” *Rouffet*, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C. R. Bard*, 157 F.3d at 1352; 48 USPQ2d at 1232. Broad conclusory statements regarding the teachings of multiple references, standing alone, are not “evidence.” *E.g., McElmurry V. Arkansas Power & Light Co.*, 995 F.2d 1576, 1578; 27 USPQ2d 1129, 1131 (Fed. Cir. 1993) (“Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact.”); *In re Sichert*, ‘566 F.2d 1154, 1164, 196 USPQ ~209; 217 (CCPA 1977).

It is clear that the authorities are unanimous in holding that it is impermissible to use the claimed invention as an instruction manual or “template” to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious. A rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Since there is no factual basis in the prior art relied on which supports the proposed combination thereof, and it is apparent that the examiner’s conclusion of obviousness is based on hindsight reconstruction of the claimed invention from isolated disparate teachings in prior art which is not concerned with the problem sought to be solved by the claimed invention, this ground of rejection is not sustainable.

It is clear that the Examiner, in making the analysis that led to the present ground of rejection, fell into the trap of hindsight reconstruction of the invention from the reference disclosures in light of applicant's specification.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

The prior art cited by the Examiner but not relied upon has been carefully reviewed. The Cosman patent is based not upon a formable patient specific mask system but instead on a standard rubber band that is stretched across the patient's anatomy, specifically to the patient's forehead. The reference does not discuss any anatomic features of the patient that the said band indexes to or is referenced to. The patent discusses the addition of skin marks but does not discuss the ability to repeatedly attach the band and therefore only discusses a single application use that would require the entire image plus diagnostic or therapeutic procedure having to be carried out without removal of the band, similar to the Kormos patent. The skin marks referenced in Cosman are routinely incorporated in such procedures to ensure that the band has not slipped during the procedure. It has not been proved feasible to use such skin marks for reference for repeat fixation again indicating that the Cosman patent is specific for a single procedure and not repeat procedures with removal of the reference between segments of a procedure or between successive procedures.

Cosman also discusses the addition of diagonal markers for stereotactic indexing during the diagnostic procedure. Although the present invention does not contemplate the exclusion of any such marker system it does not require such specificity.

In contrast, the proposed system uses a molded mask to key to the patient's anatomy specifically for the purpose of repeat fixation. It is specified that the mask be

fixed to the anatomy while being mechanically free of any other immobilization or fixation system.

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

Respectfully submitted,

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